Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in this application.

The following amendments do not constitute an admission regarding the patentability of the amended subject matter and should not be so construed. Amendments to the claims were made for purposes of more clearly stating the claimed subject matter and do not add new matter or alter the scope of the claims.

Listing of Claims

1-17 (Canceled)

18. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises; wherein the coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin of a subject for 5 second; and wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

19. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto said microprotrusions; and

drying said applied aqueous solution to form a dry agent-containing coating on said microprotrusions;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises; wherein the coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin of a subject for 5 second; and wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

20. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions; said microprotrusions adapted to pierce through the stratum corneum to a depth of less than about 500 micrometers;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises; wherein the coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin of a subject for 5 second; and wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

21. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member, said coating being less than a thickness of the microprotrusions.

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises; wherein the coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin of a subject for 5 second; and wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

22. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions, said microprotrusions having a length of less than 500 micrometers and a thickness of less than 25 micrometers;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises; wherein the coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin of a subject for 5 second; and wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

23. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member; said pharmacologically active agent selected from the group consisting of

adrenocortiocotropic hormone (ACTH (1-24)), calcitonin, desmopressin, leutinizing hormone releasing hormone (LHRH), goserelin, leuprolide, buserelin, triptorelin, parathyroid hormone (PTH), vasopressin, deamino [Val4, D-Arg8] arginine vasopressin, interferon alpha, interferon beta, interferon gamma, follicle stimulating hormone (FSH), erythoropoietin (EPO), granulocyte macrophage colony stimulating factor (GM-CSF), granulocyte colony stimulating factor (G-CSF), interleukin-10 (IL-10), glucagon, and growth regulatory factor (GRF); and

drying said applied aqueous solution to form a dry agent-containing coating on said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises; wherein the coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin of a subject for 5 second; and wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

24. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent desmopressin onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member;

wherein said agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises; wherein the coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin of a subject for 5 second; and wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

25-27 (Canceled)

28. (Withdrawn) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member in a pattern; and

drying said applied aqueous solution to form a dry agent-containing coating on said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises; and wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

29. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises; <u>wherein the coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin of a subject for 5 second;</u> and wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

30. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member;

wherein said agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 50 centipoises; wherein the coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin of a subject for 5 second; and wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

31. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member; said coating having a thickness over a surface of said member of less than 50 micrometers;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises; wherein the coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin of a subject for 5 second; and wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

32. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member; said coating having a thickness over a surface of said member of less than 25 micrometers;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises; wherein the coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin of a subject for 5 second; and wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

33. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

providing an aqueous solution comprising said pharmacologically active agent and an adjuvant;

applying said aqueous solution onto the member; and

drying said applied aqueous solution to form a dry agent-containing and adjuvant-containing coating on said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises; wherein the coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin of a subject for 5 second; and wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

34. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member; said coating comprising a loading of said pharmacologically active agent of less than 1 mg/cm^2 of area of said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises; wherein the coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin of a subject for 5 second; and wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

35. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto the member; and

drying said applied aqueous solution to form a dry agent-containing coating on said member; said coating comprising a loading of said pharmacologically active agent of less than 0.5 mg/cm^2 of area of said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises; wherein the coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin

of a subject for 5 second; and wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

36-46 (Canceled)

47. (Currently amended) A method of making a device for transdermally delivering a pharmacologically active agent, the method comprising:

providing a member having a plurality of stratum corneum-piercing microprotrusions;

applying an aqueous solution of the pharmacologically active agent onto said member by dip coating said member in said solution; and

drying said applied aqueous solution to form a dry agent-containing coating on said member;

wherein the agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C of less than about 500 centipoises; wherein the coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin of a subject for 5 second; and wherein the method provides uniformity of coating from microprotrusion to microprotrusion.

48-50 (Canceled).